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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,999	01/30/2004	Michael R.S. Hill	P-9091.06	7976
27581	7590	11/25/2005	EXAMINER	
MEDTRONIC, INC.			LAYNO, CARL HERNANDZ	
710 MEDTRONIC PARK			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55432-9924			3766	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tm

Office Action Summary	Application No. 10/768,999	Applicant(s) HILL ET AL.	
	Examiner Carl H. Layno <i>Carl H. Layno 11/22/05</i>	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-28 and 42-46 is/are allowed.
- 6) ☒ Claim(s) 29,30,33-35 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 31,32,36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/04, 5/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application Serial No. 10/207,725, filed July 29, 2002, now U.S. Patent No. 6,718,208, which is a Continuation of U.S. Application Serial No. 09/670,441, filed on September 26, 2000, now U.S. Patent No. 6,449,507, which is a Continuation in Part (CIP) of U.S. Application Serial No. 09/433,323, filed November 3, 1999, now U.S. Patent No. 6,266,564, which is a Continuation of U.S. Application Serial No. 09/070506, filed April 30, 1998, now U.S. Patent No. 6,006,134, which is a Continuation In Part (CIP) of U.S. Application Serial No. 08/640,013, filed April 30, 1996, now Abandoned.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449), which were received by the Office on June 28, 2004 and on May 4, 2005.

Drawings

3. Applicant's formal drawings were received by the Office on January 30, 2004 and have been approved by the Examiner.

Specification

4. The disclosure is objected to because of the following informalities:

-p.1, lines 1-4 of the specification, please update the priority information to reflect the fact that application 10/207,725 is now U.S Patent No. 6,718,208.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 29, 30, 33-35, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Matheny et al (US 5,651,378) (Applicant's cited prior art).

In regard to claim 29, the Matheny et al patent (US 5,651,378), cited as prior art by the Applicant, describes a method of using vagal nerve stimulation during coronary artery bypass graft (CABG) surgery (col.1, lines 1-7), whose method steps read upon applicant's claimed

steps. Specifically, Matheny et al provides an electric stimulator (not shown) including electrodes (i.e. invasive needle-type or non-invasive clip type) for attachment to the vagal nerve (col.4, lines 6-12). During surgical operations involving suturing (i.e. anastomosis), the stimulator will intermittently start and stop operation depending upon “the number of stitches required” (col.3, lines 42-49) in order to slow or temporarily stop the heart to reduce its motion.

In regard to claims 30, 33, and 34, the electrodes of Matheny et al may be located either invasively (i.e. transvascular or intracutaneous) using needle electrodes or non-invasively (i.e. transcutaneously) using clip electrodes (col.4, lines 9-12).

In regard to claims 35 and 38, during CABG surgery using the Matheny et al stimulator, Heparin, a synthesized anti-coagulant drug is administered (col.3, lines 25-27).

7. Claims 29, 30, and 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al (US 6,381,499) (Applicant’s cited prior art).

In regard to claim 29, the Taylor et al patent (US 6,381,499), cited as prior art by the Applicant, describes a vagus nerve stimulation system (Fig.22) for adjusting a pateint’s heart beat during surgery. The operation of the Taylor et al system reads upon applicant’s claimed method steps since it provides an electrical stimulating device **220** (Fig.22), provides stimulating electrodes over both the left and right vagus nerves (clip positions **#2** and **#3** – Fig.22, respectively) (col.11, lines 33-42), and intermittently starts and stops electrical stimulation through these electrodes in 10 second bursts 30 seconds apart (col.2, lines 18-22), or depending upon the surgery required (col.2, lines 30-34). For the case of anastomosis stitching or suturing

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(as above for Matheny et al), the stimulation may “be repeatedly applied for brief intervals during which time the task can be performed” (col.2, lines 35).

In regard to claim 30, clip electrodes #2 and #3 (Fig.22) appear to be in transvascular positions.

In regard to claims 39-41, the Taylor et al system (Fig.22) includes a heart pacing device 224, which is used to restart the heart by generating stimulating pulses once the stimulus is removed from the vagus nerve (col.12, lines 19-24).

Allowable Subject Matter

8. Claims 1-28 and 42-46 are allowed.
9. Claims 31, 32, 36, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 1 and 15 describe vagal nerve stimulation methods used for temporarily stopping a patient’s heartbeat. Unlike references of the prior art, applicant’s methods disclose the unique step of “automatically stopping” the stimulation of the vagus nerve. Unable to find this feature in any other reference(s) in the prior art, the Examiner deems these claims and their depending claims to be allowable.

Independent claims 42-46 also recite method claims for intermittently starting and stopping stimulation to various other heart regions (i.e. carotid sinus nerve, Purkinje fibers, AV node/HIS bundle, AV node fat pad, and SA node fat pad, respectively) to manipulate cardiac rhythm during a medical procedure. Although applicant provided many prior art references teaching the stimulation of these regions for their parasympathetic effects, none taught their usefulness in medical procedures; consequently, the Examiner also deems these claims to be allowed.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

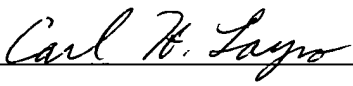
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CARL LAYNO
PRIMARY EXAMINER

CHL

11/22/2005